



43

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Patrick O. Brown and
Tidhar Dari Shalon


SERIAL NO.: Not yet assigned

FILED: Herewith

FOR: Method For Determining the Relative
Abundances of Polynucleotide
Sequences

§ **GROUP ART UNIT:** 1634
§
§
§ **EXAMINER:** Ardin Marschel
§
§ **ATTORNEY DOCKET:** STFD:009--1
§
§ (Continuing application of Serial
§ No. 08/688,488, filed July 30, 1996)
§

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INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, Applicants respectfully request that this Information Disclosure Statement be entered and the documents listed on the attached Form PTO-1449 (Exhibit A hereto) be considered by the Examiner and made of record.

In accordance with 37 C.F.R. §§ 1.97(g), (h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

Applicants wish to bring to the Examiner's attention several patent applications related to this application. United States patent application Serial No. 08/688,488 is the parent of this continuation application. United States patent application Serial No. 08/514,875 is the grandparent of this continuation application. United States patent application Serial No. 08/477,809, now United States Patent No. 5,807,522, is the great-grandparent of this application. United States patent application Serial No. 08/261,388, now abandoned, is the great-great-grandparent of this application. Three other pending patent applications claim the benefit of the filing date of great-great-grandparent application Serial No. 08/261,388. These are: (1) United States patent application Serial No. 09/001,027, a continuation of great-grandparent application Serial No. 08/477,809, (2) an application filed November 19, 1998, Serial No. not yet assigned, which is a continuation of application Serial No. 09/001,027, and (3) an application filed November 10, 1998, Serial No. not yet assigned, which is a continuation of grandparent application Serial No. 08/514,875.

The Examiner referred to several references in great-grandparent application Serial No. 08/477,809, which are listed on the attached Form PTO-1449 as references A17, A32, A52-A55, C16 and C32. The Examiner referred to several references in grandparent application Serial No. 08/514,875, which are listed on the attached Form PTO-1449 as references A17, A32, A49, A50,

A53, A55, B8, C8, C12, C16, C21, C24, C32 and C34. The Examiner referred to several references in parent application Serial No. 08/688,488, which are listed on the attached Form PTO-1449 as references A50, A51, A53, A55, A56, C12, C16, C17 and C21.

Applicants also wish to bring to the Examiner's attention two related foreign patent applications. First, Applicants refer to PCT patent application WO 95/35505, which claimed priority from the great-grandparent of this application (i.e., Serial No. 08/477,809). Applicants enclose, as Exhibit B hereto, a copy of the International Search Report in that application, which listed five references. Those references are listed on the attached Form PTO-1449 as references A2, A22, A26, A28 and A32. Second, Applicants refer to European patent application 95 92 3921.1, which claims priority from the great-grandparent of this application (i.e., Serial No. 08/477,809). Applicants enclose, as Exhibit C hereto, a copy of the Supplementary European Search Report in that application, which lists three references. Those references are listed on the attached Form PTO-1449 as references B8, B9 and C43. Applicants enclose, as Exhibit D hereto, a copy of a Communication Pursuant to Article 96(2) and Rule 51(2), dated March 26, 1998, in European patent application EP 95 92 3921, which lists an additional reference at paragraph 5. That reference is listed on the attached Form PTO-1449 as reference B10.

The present Information Disclosure Statement is being filed prior to the receipt of a first Official Action reflecting an examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R. § 1.97(b). No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Commissioner is hereby

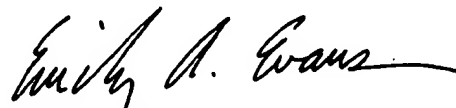
authorized to deduct said fees from Arnold, White & Durkee Deposit Account

No. 01-2508/STFD/EVE.

This application is a continuation application of Serial No. 08/688,488, filed July 30, 1996, which is a continuation-in-part of Serial No. 08/514,875, filed August 14, 1995, which is a continuation-in-part of Serial No. 08/477,809, filed June 7, 1995 (now U.S. patent No. 5,807,522), which is a continuation-in-part of Serial No. 08/261,388, filed June 17, 1994 (now abandoned), each of which is relied upon for an earlier filing date under 35 U.S.C. § 120. All of the documents listed on the Form PTO-1449 that is attached as Exhibit A hereto (except references A57-A61, B11-B15 and C45-C46) were either cited by or submitted to the Patent and Trademark Office in those prior applications. Accordingly, pursuant to 37 C.F.R. § 1.98(d), Applicants enclose copies of references A57-A61, B11-B15 and C45-C46, and respectfully refer the Examiner to the files of application Serial Nos. 08/688,488, 08/514,875, 08/477,809 and 08/261,388 for copies of the other listed references.

Applicants respectfully request that the listed documents be made of record in the present case.

Respectfully submitted,

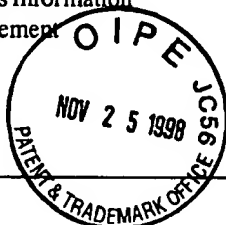


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Date: November 24, 1998

Form PTO-1449 (modified)
List of Patents and Publications
For Applicant's Information
Disclosure Statement



ATTY. DOCKET NO.
STFD 009--1

SERIAL NO.
Not yet assigned
(Continuation of 08/688,488)

APPLICANTS: P.O. Brown and T.D. Shalon

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herewith

GROUP
1634

U.S. PATENT DOCUMENTS

EXAM. INIT.	REF. DES.	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A1	3,730,844	05/01/73	Gilham, et al.	195	103.5R	
	A2	4,071,315	01/31/78	Chateau	23	230B	
	A3	4,486,539	12/04/84	Ranki, et al.	436	504	
	A4	4,556,643	12/03/85	Paau, et al.	436	501	
	A5	4,563,419	01/07/86	Ranki, et al.	435	6	
	A6	4,670,380	06/02/87	Dattagupta	435	6	

FOREIGN PATENT DOCUMENTS

EXAM. INIT.	REF. DES.	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION YES/NO
	B1	WO 90/03382	04/05/90	PCT			
	B2	WO 95/00530	01/05/95	PCT			
	B3	WO 95/15970	06/15/95	PCT			

OTHER ART (Author, Title, Journal, Volume, Pertinent Pages, & Date)

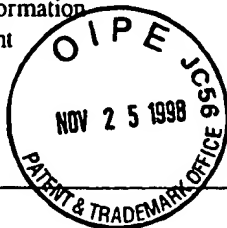
	C1	Billings <i>et al.</i> , "New Techniques for Physical Mapping of the Human Genome," <i>FASEB</i> , 5:28-34 (1991).
	C2	Chee, <i>et al.</i> , "Accessing Genetic Information with High-Density DNA Arrays", <i>Science</i> , 274:610-614 (1996).
	C3	Drmanac <i>et al.</i> , "DNA Sequence Determination by Hybridization: A Strategy for Efficient Large-Scale Sequencing," <i>Science</i> , 260:1649-1652 (1993).
	C4	Drmanac <i>et al.</i> , "Laboratory Methods: Reliable Hybridization of Oligonucleotides as Short as Six Nucleotides," <i>DNA and Cell Biology</i> , 9:527-534 (1990).
	C5	Drmanac <i>et al.</i> , "Sequencing by Hybridization: Towards an Automated Sequencing of One Million M13 Clones Arrayed on Membranes," <i>Electrophoresis</i> , 13:566-573 (1992).
	C6	Ekins, <i>et al.</i> , "Multianalyte Immunoassay: The Immunological 'Compact Disk' of the Future", <i>J. Clinical Immunoassay</i> , 13(4):169-181 (1990).

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U.S. PATENT DOCUMENTS

EXAM. INIT.	REF. DES.	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A7	4,677,054	06/30/87	White et al.	435	6	
	A8	4,683,195	07/28/87	Mullis, et al.	435	6	
	A9	4,683,202	07/28/87	Mullis	435	91	
	A10	4,716,106	12/29/87	Chiswell	435	6	
	A11	4,731,325	03/15/88	Palva, et al.	435	6	
	A12	4,755,458	07/05/88	Rabbani, et al.	435	5	

FOREIGN PATENT DOCUMENTS

EXAM. INIT.	REF. DES.	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION YES/NO
	B4	WO 95/21944	08/17/95	PCT			
	B5	WO 95/25116	9/21/95	PCT			
	B6	WO 96/17958	06/13/96	PCT			

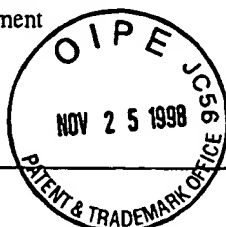
OTHER ART (Author, Title, Journal, Volume, Pertinent Pages, & Date)

	C7	Fodor <i>et al.</i> , "Light-Directed, Spatially Addressable Parallel Chemical Synthesis," <i>Science</i> , <u>251</u> :767-773 (1991).
	C8	Guo, <i>et al.</i> , "Direct Fluorescence Analysis of Genetic Polymorphisms by Hybridization with Oligonucleotide Arrays on Glass Supports", <i>Nucleic Acids Research</i> , <u>22</u> :5456-5465 (1994).
	C9	Johnston, <i>et al.</i> , "Chemistry of High Density Arrays: Factors Impacting Issues of Complexity", (Abstract) <i>Microbial & Comparative Genomics</i> , <u>1</u> :235 (1996).
	C10	Kallioniemi <i>et al.</i> , "Comparative Genomic Hybridization for Molecular Cytogenetic Analysis of Solid Tumors," <i>Science</i> , <u>258</u> :818-821 (1992).
	C11	Kallioniemi <i>et al.</i> , "Optimizing Comparative Genomic Hybridization for Analysis of DNA Sequence Copy Number Changes in Solid Tumors," <i>Genes, Chromosomes & Cancer</i> , <u>10</u> :231-243 (1994).
	C12	Khrapko <i>et al.</i> , "A Method for DNA Sequencing by Hybridization with Oligonucleotide Matrix," <i>DNA Sequencing and Mapping</i> , <u>1</u> :375-388 (1991).

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EXAM. INIT.	REF. DES.	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A13	4,767,700	08/30/88	Wallace	435	6	
	A14	4,868,104	09/19/89	Kurn, et al.	435	6	
	A15	4,868,105	09/19/89	Urdea, et al.	435	6	
	A16	4,921,805	05/01/90	Gebeyehu, et al.	435	270	
	A17	4,981,783	01/01/91	Augenlicht	435	6	
	A18	5,013,669	05/07/91	Peters, Jr. et al.	436	518	

FOREIGN PATENT DOCUMENTS

EXAM. INIT.	REF. DES.	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION YES/NO
	B7	EPO 721016A2	07/10/96	EPO			
	B8	WO 92/10588	06/25/92	PCT			
	B9	WO 93/22680	11/11/93	PCT			

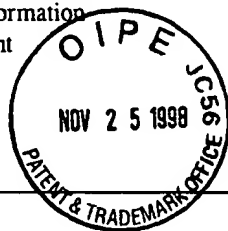
OTHER ART (Author, Title, Journal, Volume, Pertinent Pages, & Date)

	C13	Kozal, <i>et al.</i> , "Extensive Polymorphisms Observed in HIV-1 Clade B Protease Gene using High-Density Oligonucleotide Arrays", <i>Nature Medicine</i> , 2:753-759 (1996).
	C14	Kreiner, "Rapid Genetic Sequence Analysis Using a DNA Probe Array System," <i>American Laboratory</i> (March 1996).
	C15	Lehrach <i>et al.</i> , "Hybridization Fingerprinting in Genome Mapping and Sequencing," in <i>Genome Analysis</i> , Volume I: Genetic and Physical Mapping. (K.E. Davies & S.M. Tilgham, Eds.) Cold Spring Harbor Laboratory Press, pp. 39-81 (1990).
	C16	Lennon <i>et al.</i> , "Hybridization Analyses of Arrayed cDNA Libraries," <i>Trends In Genetics</i> , 7:314-317 (1991).
	C17	Maskos, <i>et al.</i> , "A Study of Oligonucleotide Reassociation Using Large Arrays of Oligonucleotides Synthesised on a Glass Support", <i>Nucleic Acids Research</i> , 21:4663-4669 (1993)
	C18	Medlin, "The Amazing Shrinking Laboratory", <i>Environmental Health Perspectives</i> , 103:244-246 (1995)

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1634**U.S. PATENT DOCUMENTS**

EXAM. INIT.	REF. DES.	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A19	5,028,545	07/02/91	Soini	436	501	
	A20	5,064,754	11/12/91	Mills	435	6	
	A21	5,091,652	02/25/92	Mathies, et al.	250	458.1	
	A22	5,100,777	03/31/92	Chang	435	7.24	
	A23	5,143,854	09/01/92	Pirrung et al.	436	518	
	A24	5,185,243	02/09/93	Ullman, et al.	435	6	

FOREIGN PATENT DOCUMENTS

EXAM. INIT.	REF. DES.	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION YES/NO
	B10	WO 89/10977	05/02/89	PCT			
	B11	WO 93/09668	05/27/93	PCT			
	B12	WO 95/11995	05/04/95	PCT			

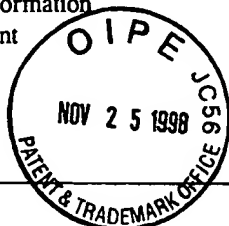
OTHER ART (Author, Title, Journal, Volume, Pertinent Pages, & Date)

	C19	Nguyen <i>et al.</i> , "Differential Gene Expression in the Murine Thymus Assayed by Quantitative Hybridization of Arrayed cDNA Clones," <i>Genomics</i> , <u>29</u> :207-216 (1995).
	C20	Nowak, "Entering the Postgenome Era", <i>Science</i> , <u>270</u> :368-369 (1995).
	C21	Pease, <i>et al.</i> , "Light-generated Oligonucleotide Arrays for Rapid DNA Sequence Analysis", <i>Proc. Natl. Acad. Sci. USA</i> , <u>91</u> :5022-5026 (May 1994).
	C22	Pietu, <i>et al.</i> , "Novel Gene Transcripts Preferentially Expressed in Human Muscles Revealed by Quantative Hybridization of a High Density cDNA Array", <i>Genome Research</i> , <u>6</u> :492-503 (1996).
	C23	Regalado, "DNA - Chips in Genomics", <i>Start Up</i> , <u>1</u> :24-30 (1996).
	C24	Sambrook, <i>et al.</i> , "Molecular Cloning, A Laboratory Manual", <i>Cold Spring Harbor Press</i> , pp.7.39-7.52 (1989).

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1634**U.S. PATENT DOCUMENTS**

EXAM. INIT.	REF. DES.	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A25	5,188,963	02/23/93	Stapleton	435	299	
	A26	5,200,312	04/06/93	Oprandy	435	5	
	A27	5,202,231	04/13/93	Drmanac, et al.	435	6	
	A28	5,204,268	04/20/93	Matsumoto	436	44	
	A29	5,242,974	09/07/93	Holmes	525	54.11	
	A30	5,252,296	10/12/93	Zuckerman, et al.	422	116	

FOREIGN PATENT DOCUMENTS

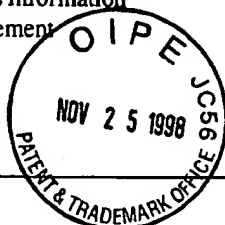
EXAM. INIT.	REF. DES.	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION YES/NO
	B13	WO 97/10365	03/20/97	PCT			
	B14	EP 0717113 A2	06/19/96	EPO			
	B15	GB 2,248,840	06/07/90	United Kingdom			

OTHER ART (Author, Title, Journal, Volume, Pertinent Pages, & Date)

	C25	Schena, et al., "Structure of Homeobox-Leucine Zipper Genes Suggests a Model for the Evolution of Gene Families", <i>Proc. Natl. Acad. Sci. USA</i> , <u>91</u> :8393-8397 (Aug. 1994).
	C26	Schena, "Genome Analysis with Gene Expression Microarrays", <i>BioEssays</i> , <u>18</u> :427-431 (1996).
	C27	Schena, et al., "Quantitative Monitoring of Gene Expression Patterns with a Complementary DNA Microarray," <i>Science</i> , <u>270</u> :467-470 (1995).
	C28	Schena, et al., "Parallel Human Genome Analysis: Microarray-based Expression Monitoring of 1000 Genes", <i>Proc. Natl. Acad. Sci. USA</i> , <u>93</u> :10614-10619 (Oct. 1996).
	C29	Schena, et al., "The <i>HAT4</i> Gene of <i>Arabidopsis</i> Encodes a Developmental Regulator", <i>Genes & Development</i> , <u>7</u> :367-379 (1993).
	C30	Schena, et al., "HD-Zip Proteins: Members of an <i>Arabidopsis</i> Homeodomain Protein Superfamily", <i>Proc. Natl. Acad. Sci. USA</i> , <u>89</u> :3894-3898 (May 1992).

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	A31	5,328,824	07/12/94	Ward, et al.	435	6	
	A32	5,338,688	08/16/94	Deeg, et al.	436	180	
	A33	5,348,855	09/20/94	Dattagupta, et al.	435	6	
	A34	5,389,512	02/14/95	Sninsky, et al.	435	5	
	A35	5,434,049	07/18/95	Okano, et al.	435	6	
	A36	5,445,934	08/29/95	Fodor, et al.	435	6	

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OTHER ART (Author, Title, Journal, Volume, Pertinent Pages, & Date)

	C31	Schober, <i>et al.</i> , "Accurate High-Speed Liquid Handling of Very Small Biological Samples", <i>Biotechniques</i> , <u>15</u> (2):324-329 (1993).
	C32	Shalon, "DNA Micro Arrays: A New Tool for Genetic Analysis" (Dec. 1995) (Ph.D. Thesis, Stanford University).
	C33	Shalon, <i>et al.</i> , "A DNA Microarray System for Analyzing Complex DNA Samples Using Two-Color Fluorescent Probe Hybridization", <i>Genome Research</i> , <u>6</u> :639-645 (July 1996).
	C34	Southern, <i>et al.</i> , "Analyzing and Comparing Nucleic Acid Sequences by Hybridization to Arrays of Oligonucleotides: Evaluation Using Experimental Models", <i>Genomics</i> , <u>13</u> :1008-1017 (1992).
	C35	Woolley, <i>et al.</i> , "Ultra-high-speed DNA Fragment Separations Using Microfabricated Capillary Array Electrophoresis Chips", <i>Proc. Natl. Acad. Sci. USA</i> , <u>91</u> :11348-11352 (Nov. 1994).
	C36	Zhao <i>et al.</i> , "High-Density cDNA Filter Analysis: A Novel Approach for Large-Scale, Quantitative Analysis of Gene Expression," <i>Science</i> , <u>156</u> :207-213 (1995).

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	A37	5,472,842	12/05/95	Stokke et al.	435	6	
	A38	5,474,895	12/12/95	Ishii, et al.	435	6	
	A39	5,510,270	04/23/96	Fodor, et al.	436	518	
	A40	5,512,430	04/30/96	Gong	435	5	
	A41	5,514,543	05/07/96	Grossman, et al.	435	6	
	A42	5,514,785	05/07/96	Van Ness, et al.	536	22.1	

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EXAM. INIT.	REF. DES.	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION YES/NO

OTHER ART (Author, Title, Journal, Volume, Pertinent Pages, & Date)

	C37	Hewlett-Packard, "Peripherals Index," from <i>HP Fax Information Retrieval Support Technology</i> , Phone No. 1-800-333-1917, 6 pages.
	C38	Hewlett-Packard, "Document #9651", from <i>HP Fax Information Retrieval Support Technology</i> , Phone No. 1-800-333-1917, 3 pages.
	C39	Hewlett-Packard, "Document #5322", from <i>HP Fax Information Retrieval Support Technology</i> , Phone No. 1-800-333-1917, 5 pages.
	C40	Hewlett-Packard, "Document #5330," from <i>HP Fax Information Retrieval Support Technology</i> , Phone No. 1-800-333-1917, 5 pages.
	C41	NIH grant application of P.O. Brown submitted 1992.
	C42	J.A., "Putting Genes on a Chip", <i>Science</i> , <u>264</u> : (1994)

EXAMINER

DATE CONSIDERED

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Form PTO-1449 (modified)List of Patents and Publications
For Applicant's Information
Disclosure Statement**ATTY. DOCKET NO.**
STFD 009-1**SERIAL NO.**
Not yet assigned
(Continuation of 08/688,488)

APPLICANTS: P.O. Brown and T.D. Shalon

FILING DATE
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1634**U.S. PATENT DOCUMENTS**

EXAM. INIT.	REF. DES.	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A43	5,516,641	05/14/96	Ullman, et al.	435	6	
	A44	5,518,883	05/21/96	Soini	435	6	
	A45	5,545,531	08/13/96	Rava, et al.	435	6	
	A46	5,556,748	09/17/96	Douglas	435	6	
	A47	5,556,752	09/17/96	Lockhart, et al.	435	6	
	A48	5,578,832	11/26/96	Trulson, et al.	250	458.1	

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EXAM. INIT.	REF. DES.	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION YES/NO

OTHER ART (Author, Title, Journal, Volume, Pertinent Pages, & Date)

	C43	Eggers, <i>et al.</i> , "A Microchip for Quantitative Detection of Molecules Utilizing Luminescent and Radioisotope Reporter Groups," <i>BioTechniques</i> , <u>17</u> :516-525 (Sept. 1994).
	C44	De Risi, <i>et al.</i> , "Use Of a cDNA Microarray to Analyse Gene Expression Patterns In Human Cancer," <i>Nature Genetics</i> , <u>14</u> :457-460 (Dec. 1996).
	C45	McGall, <i>et al.</i> , "The Efficiency of Light-Directed Synthesis of DNA Arrays on Glass Substrates", <i>J. Am. Chem. Soc.</i> , <u>119</u> :5081-5090 (1997).
	C46	Pirrung, <i>et al.</i> , "Comparison of Methods for Photochemical Phosphoramidite-Based DNA Synthesis," <i>J. Org. Chem.</i> , <u>60</u> :6270-6276 (1995).

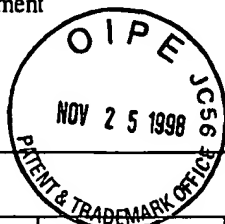
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1634**U.S. PATENT DOCUMENTS**

EXAM. INIT.	REF. DES.	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A49	5,412,087	05/02/95	McGall, et al.	536	24.3	
	A50	5,474,796	12/12/95	Brennan	427	2.13	
	A51	5,563,060	10/08/96	Hozier	435	240.23	
	A52	4,591,570	05/27/86	Chang	436	518	
	A53	5,605,662	02/25/97	Heller, et al.	422	68.1	
	A54	5,200,051	04/06/93	Cozzette, et al.	204	403	

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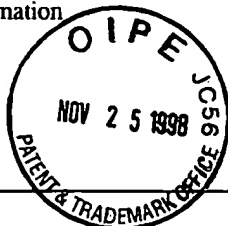
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EXAM. INIT.	REF. DES.	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A55	5,252,743	10/12/93	Barrett, et al.	548	303.7	
	A56	5,744,305	04/28/98	Fodor, et al.	435	6	
	A57	5,800,992	09/01/98	Fodor, et al.	435	6	
	A58	5,795,716	08/18/98	Chee, et al.	435	6	
	A59	5,677,195	10/14/97	Winkler, et al.	436	518	
	A60	5,665,549	09/09/97	Pinkel, et al.	435	6	
	A61	5,830,645	11/03/98	Pinkel, et al.	435	6	

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